REMARKS

In response to the office action dated August 26, 2009, Applicants have added new claims 18-23. Support for new claim 18 can be found at, e.g., paragraph [0019] of the specification. Support for new claim 19 can be found at, e.g., paragraph [0034] of the specification. Support for new claim 20 can be found at, e.g., paragraphs [0032] and [0033] of the specification. Support for new claim 21 can be found at, e.g., paragraph [0054] of the specification. Support for new claim 22 can be found at, e.g., paragraph [0043] of the specification. Support for new claim 23 can be found at, e.g., paragraph [0024] of the specification. Applicants have also amended withdrawn claim 7 so that it now depends from claim 1. Applicants reserve the right to rejoin claim 7 upon allowance of claim 1. No new matter has been introduced by the above amendments. Claims 1-6 and 16-23 are presented for examination.

Claims 1-6, 16 and 17 are rejected under 35 U.S.C. §102(b) as anticipated by, or under 35 U.S.C. §102(b) as obvious from, Shimagaki et al., U.S. Patent No. 6,103,117 ("Shimagaki").

Independent claim 1 is discussed first. It recites a polysulfone permselective hollow fiber membrane bundle that contains poly(vinylpyrrolidone). The membrane bundle shows a hydrogen peroxide-eluting amount of 5 ppm or less with respect to the mass of the hollow fiber membrane when measured according to the procedure recited in claim 1.

The Office action states that

> "Shimagaki … does not explicitly state the amount of hydrogen peroxide that can be eluded from the membrane, or its UV absorbance. However, since the membrane otherwise has the same composition as well the starting materials, the residue hydrogen peroxide (from PVP starting material) as well as the UV absorbance resulting from it are assumed to be inherently the same as that of the applicant's."

See page 2, last paragraph. The Examiner is reminded that "[t]he fact that a certain result or characteristic **may** occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *See* MPEP 2112 IV; emphasis in original. To reply upon the theory of inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows

from the teachings of the applied prior art." *Id.*; emphasis in original. However, the Examiner has provided no such showing. The mere fact that the membrane bundles disclosed in Shimagaki **might** exhibit a hydrogen peroxide-eluting amount of 5 ppm or less with respect to the mass of the hollow fiber membrane is not sufficient to support the determination that the membrane bundles disclosed in Shimagaki **necessarily** exhibit such a hydrogen peroxide-eluting amount.

In addition, according to the specification of the present application, a hollow fiber membrane bundle that shows a hydrogen peroxide-eluting amount of 5 ppm or less can be obtained by carrying out at least one or more of the following manufacturing processes: (1) using a poly(vinylpyrrolidone) containing 300 ppm or less of hydrogen peroxide as a starting material (*see, e.g.*, paragraph [0019]); (2) kneading at least the poly(vinylpyrrolidone) in an inert gas before dissolving the poly(vinylpyrrolidone) in a solvent (*see, e.g.*, paragraph [0034]);[1] (3) dissolving the poly(vinylpyrrolidone) in a solvent in an inert gas to form a solution, in which at least some of the oxygen dissolved in the solvent is optionally replaced by the inert gas (*see, e.g.*, paragraphs [0032] and [0033]); (4) washing the bundle after the bundle is formed but before drying the bundle to remove hydrogen peroxide (*see, e.g.*, paragraph [0054]); (5) drying the bundle by irradiating the bundle with microwave under a reduced pressure (*see, e.g.*, paragraph [0043]); and (6) crosslinking the bundle in an inert gas (*see, e.g.*, paragraph [0024]). These processes can minimize the amount of hydrogen peroxide in a membrane bundle, which in turn exhibits a hydrogen peroxide-eluting amount of 5 ppm or less in the elution test recited in claim 1.

By contrast, Shimagaki is entirely silent regarding any of processes (1)-(6) described above, or any measure that would reduce the amount of hydrogen peroxide in a membrane bundle. Indeed, Shimagaki does not realize the need to reduce hydrogen peroxide in a membrane bundle. For example, Shimagaki describes dissolving its starting materials in a solvent without using an inert gas. *See, e.g.*, column 14, lines 58-62. As another example, Shimagaki describes drying its membrane bundle in air under atmospheric pressure. *See, e.g.*, column 14, line 67 to column 15, line 3. The present specification teaches that a membrane

[1] According to the present specification, contacting poly(vinylpyrrolidone) with oxygen can lead to deterioration of poly(vinylpyrrolidone), which generates hydrogen peroxide. *See, e.g.*, paragraph [0034]. Using the inert gas in the manufacturing processes can prevent contact between poly(vinylpyrrolidone) and oxygen, thereby minimizing generation of hydrogen peroxide. *Id.*

bundle prepared by such a process would contain a higher amount of hydrogen peroxide due to oxidation. *See, e.g.*, paragraphs [0032] and [0043]. Thus, it would have been apparent to one skilled in the art that the membrane bundles described in Shimagaki, which are prepared without any measure to reduce hydrogen peroxide, generally contain more hydrogen peroxide than the membrane bundle recited in claim 1, which is prepared by a process with measures to reduce hydrogen peroxide. In other words, contrary to the Examiner's assertion, one skilled in the art would reasonably expect that the membrane bundles described in Simagaki in general are different in composition (i.e., containing more hydrogen peroxide) from the membrane bundle recited in claim 1. As a result, it would have been apparent that the membrane bundles disclosed in Shimagaki would **not necessarily** exhibit a hydrogen peroxide-eluting amount of 5 ppm or less, as recited in claim 1.

The Office action asserts that "there is no evidence that the reference membrane has residual hydrogen peroxide in an amount more than 5 ppm, or that it will show any more than 5 ppm of hydrogen peroxide when tested using the recited procedure." *See* page 3, 2nd paragraph. This clearly is incorect. As discussed above, according to the present specification, the membrane bundle recited in claim 1 can be obtained by using at least one or more of processes (1)-(6). The membrane bundle thus obtained contains a reduced amount of hydrogen peroxide and therefore shows a reduced amount of hydrogen peroxide (*i.e.*, 5 ppm or less) in the elution test recited in claim 1. By contrast, as discussed above, because the membrane bundles described in Shimagaki are prepared without any measure to reduce hydrogen peroxide, they generally contain more hydrogen peroxide than the membrane bundle recited in claim 1 and therefore would have been expected to exhibit a hydrogen peroxide-eluting amount of more than 5 ppm in the elution test recited in claim 1.

In addition, the present specification discloses several comparative examples which do not result in a membrane bundle that exhibits a hydrogen peroxide-eluting amount of 5 ppm or less as recited in claim 1. In particular, Comparative Example 1 describes a membrane bundle made in the same manner as Example 1 except that (1) poly(vinylpyrrolidone) containing 500 ppm of hydrogen peroxide was used as a raw material, (2) kneading and dissolution was not performed under an inert gas, (3) the membrane bundle was dried by irradiation with microwave under an atmospheric pressure. Comparative Example 2 describes a membrane bundle made in

the same manner as Comparative Example 1 except that, among others, washing of the membrane bundle was not performed. Comparative Examples 3 describes a membrane bundle by a process in which, among others, (1) no kneading was performed, (2) dissolution of the starting materials were not performed in an inert gas, and (3) the membrane bundle was dried by irradiation with microwave under an atmospheric pressure. The results show that the membrane bundles described in Comparative Examples 1-3 respectively exhibited a hydrogen peroxide-eluting amount of up to 8 ppm, 11 ppm, and 15 ppm (*see* Table 1) in the elution test recited in claim 1, which are higher than 5 ppm or less as recited in claim 1.

Thus, contrary to the Examiner's assertion, the present specification has provided ample evidence that membrane bundles described in Shimagaki could very well exhibit a hydrogen peroxide-eluting amount of more than 5 ppm in the elution test recited in claim 1.

For at least the reasons set forth above, claim 1 is not anticipated by Shimagaki.

Nor is claim 1 rendered obvious by Shimagaki. Indeed, as discussed above, Shimagaki does not disclose any of processes (1)-(6) described above or any other measures to reduce the amount of hydrogen peroxide in its membrane bundles. There is nothing in Shimagaki that would have prompted one skilled in the art to modify its process of manufacturing a membrane bundle to reduce hydrogen oxide therein. Thus, it would not have been obvious to one skilled in the art to modify the manufacturing process described in Shimagaki to prepare a membrane bundle that has a reduced amount of hydrogen oxide so that the membrane bundle would exhibit a hydrogen peroxide-eluting amount of 5 ppm or less in the elution test recited in claim 1. In other words, the Examiner has not established a *prima facie* case of obviousness. Thus, claim 1 would not have been obvious from Shimagaki.

In sum, claim 1 is not anticipated or rendered obvious by Shimagaki. As claims 2-6, 16, and 17 depend from claim 1, they also are not anticipated or rendered obvious by Shimagaki. Accordingly, Applicants request reconsideration and withdrawal of these rejections.

Applicants submit that this application is now in condition for allowance, an action of which is respectfully requested.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; and (b) made

arguments for the patentability of some claims does not mean that there are not other good reasons for the patentability of those claims and other claims.

The $490.00 fee for a Petition for Two-Month Extension of Time is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization.

Please apply any other charges to deposit account 06-1050, referencing Attorney's Docket No. 19461-0006US1.

Respectfully submitted,

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